THE QIMR BERGHOFER MEDICAL RESEARCH INSTITUTE

HUMAN RESEARCH ETHICS COMMITTEE

TERMS OF REFERENCE

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1.1. Scope of Responsibilities

1.1.1. The QIMR Berghofer Medical Research Institute-Human Research Ethics Committee (QIMR Berghofer-HREC) is a committee established by the Council of the Queensland Institute of Medical Research (Council), to ensure maintenance of ethical standards in research and compliance with regulatory guidelines. QIMR Berghofer-HREC reports to the Council.

1.1.2. The QIMR Berghofer-HREC is assisted by the Scientific Subcommittee (QIMR Berghofer-HSSC) and the Clinical Trial Protocol Committee (QIMR Berghofer-CTPC). These subcommittees provide advice on scientific, technical and clinical aspects of human research protocols and clinical trials, and on compliance with regulatory requirements. Both subcommittees are appointed by the QIMR Berghofer-HREC and the Director of QIMR Berghofer and report to the QIMR Berghofer-HREC.

1.1.3. The QIMR Berghofer-HREC is guided by: "*World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects", "The National Statement on Ethical Conduct in Research Involving Humans", "The Values and Ethics: Guidance for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research", "Human Research Ethics Committees and the Therapeutic Goods Legislation"*, "*The Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) – Annotated with TGA Comments*", "*Guidelines Under section 95 of the* Privacy Act 1988*", "Guidelines approved under Section 95A of the Privacy Act 1988*", "*QIMR Berghofer Medical Research Institute Conflict of Interest Policy*", and "*QIMR Berghofer Medical Research Institute Policy on Quality Management of Clinical Studies*", as amended from time to time.

1.1.4. The QIMR Berghofer-HREC shall:

1.1.4.1. Advise the Council on policy requirements relating to the *National Statement*, and any other relevant State, Territory and Commonwealth legislation relating to human experimentation.

1.1.4.2. Consider research protocols involving human experimentation carried out:

1.1.4.2.1. Within the premises of QIMR Berghofer, including both QIMR Berghofer and non-QIMR Berghofer scientific groups;

1.1.4.2.2. By QIMR Berghofer personnel, whether intra- or extra-mural;

1.1.4.2.3. By some organisations for whom QIMR Berghofer has agreed to act.

1.1.4.2.4. By organisations, with whom QIMR Berghofer has a Memorandum of Understanding.

1.1.4.2.5. By organisations beyond those with whom the Institute has established a Memorandum of Understanding, pursuant to mutual recognition arrangements.

1.1.4.3. Carry out ethical reviews and approve, request amendment of, or reject a research proposal on ethical grounds, monitor, review, and if necessary, withdraw approval for any research project.

1.1.4.4. Consider whether expert advice is required for the proper consideration of a particular proposal, and where required, the Committee may recommend to QIMR Berghofer that an appropriate expert/s be commissioned to provide that advice.

1.1.4.5. Ensure that, where a project involves more than one institution, the project has met ethical approval from each participating institution.

1.1.4.6. Maintain a register of the research protocols submitted to the QIMR Berghofer-HREC.

1.1.4.7. Provide information and reports to the NHMRC and NHMRC principal committees on request.

1.1.4.8. Provide information and reports to the Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Aged Care, where appropriate.

1.1.4.9. Where the conditions of a grant involve compliance with the requirements of any other regulatory agency, particularly an overseas agency, the QIMR Berghofer-HREC will endeavour to meet those requirements. Investigators should notify the QIMR Berghofer-HREC of the requirements before the grant is accepted.

1.2. Accountability

The QIMR Berghofer-HREC is accountable to the Council. The QIMR Berghofer-HREC, before granting approval to a research study involving humans, must be satisfied that the protocol conforms to:

1.2.1. The NHMRC "*National Statement*";

1.2.2. Where relevant, the CPMP/ICH "*Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95)*" adopted by the TGA;

1.2.3. Any requirements of relevant Commonwealth or State/Territory laws;

1.2.4. Where relevant, overseas regulatory requirements.

1.3. Mechanisms of Reporting

Formal mechanisms of reporting include the following:

1.3.1. Minutes of all QIMR Berghofer-HREC meetings are provided to the QIMR Berghofer management/Director's Consultative Committee for consideration, and the Council for consideration and endorsement.

1.3.2. QIMR Berghofer-HREC Annual Compliance Report is provided to the Australian Health Ethics Committee of the National Health and Medical Research Council (NHMRC-AHEC).

1.3.3. Submissions are provided to Council as requested by Council or initiated by QIMR Berghofer-HREC.

2. COMPOSITION AND MEMBERSHIP OF THE QIMR BERGHOFER-HREC

2.1. The QIMR Berghofer-HREC Chairperson and Deputy Chairperson

2.1.1. Both the Chairperson and Deputy Chairperson of the QIMR Berghofer-HREC are appointed by the Council.

2.1.2. In the absence of the Chairperson, the Deputy Chairperson will perform the duties of the Chairperson.

2.1.3. In the absence of both the Chairperson and Deputy Chairperson, the Chairperson may appoint an Acting Chairperson.

2.2. The QIMR Berghofer -HREC Secretary

2.2.1. The QIMR Berghofer-HREC Secretary is an employee of QIMR Berghofer and provides administrative advice on the Institute's process of ethics review of research projects.

2.2.2. The Secretary reports to the Chairperson of the QIMR Berghofer-HREC in matters related to the activities of the Committee and to the QIMR Berghofer Regulatory Affairs Manager regarding administrative issues.

2.3. Membership of the QIMR Berghofer -HREC

The QIMR Berghofer-HREC is established in accordance with the prescriptions as set out in the "*National Statement".* The QIMR Berghofer-HREC includes at least one of each of the following:

2.3.1. A Chairperson;

2.3.2. A laywoman, who has no affiliation with QIMR Berghofer and does not currently engage in medical, scientific, legal or academic work;

2.3.3. A layman, who has no affiliation with QIMR Berghofer and does not currently engage in medical, scientific, legal or academic work;

2.3.4. A person who performs pastoral care in a community, for an example, an Aboriginal elder, or a minister of religion;

2.3.5. At least two people with current research experience that is relevant to research proposals considered by the QIMR Berghofer-HREC;

2.3.6. A person with knowledge of, and current experience in, the professional care, counselling or treatment of people;

2.3.7. A lawyer, who is not engaged to advise QIMR Berghofer;

2.4. Terms and Conditions of Appointment of Members

2.4.1. QIMR Berghofer-HREC members are appointed by the Council. All changes to the QIMR Berghofer-HREC membership are communicated to the NHMRC, AHEC, and other official research regulatory bodies as required.

2.4.2. In general, vacancies on the QIMR Berghofer-HREC are advertised via publications such as QIMR Berghofer's "*LifeLab"*, Queensland Health's "*Healthmatters"*, UQ's "*University News"*, etc.

2.5. Period of Appointment

2.5.1. QIMR Berghofer -HREC members are normally appointed for a three-year term.

2.5.2. A retiring member may be re-appointed. Appointments to fill casual vacancies are for the balance of the original appointee's term.

2.5.3. Appointment may be terminated by either party after two months notice given in writing.

2.6. Conditions of Appointment

2.6.1. Members are appointed as individuals for their knowledge, qualities, expertise and relevant experience not as representatives of any organization, group, or opinion.

2.6.2. Before appointment, members acknowledge in writing their acceptance of the terms of reference of the QIMR Berghofer-HREC and any requirements for confidentiality, privacy and training/professional development required by QIMR Berghofer.

2.6.3. Members receive a formal notice of appointment and assurances that they will be covered by QIMR Berghofer insurance policies as they relate to professional indemnity whilst performing the business of QIMR Berghofer-HREC.

2.6.4. Members undertake appropriate induction as outlined in the QIMR Berghofer-HREC Member Induction Manual (*Induction Manual*) .

2.6.5. Members attend continuing education or training programs (as listed in the *Induction Manual*) in research ethics at least every three years.

2.7. Remuneration

2.7.1. All essential and necessary expenses incurred by members in carrying out their QIMR Berghofer-HREC duties will be reimbursed by QIMR Berghofer, on production of original receipts.

2.7.2. Internet access may be provided to the primary place of residence to members, who are not staff of QIMR Berghofer or co-located entities to enable review of electronic protocols.

2.7.3. Parking will be provided at Herston for members who are not staff of QIMR Berghofer or co-located entities while attending on QIMR Berghofer-HREC business.

3. WRITTEN PROPOSALS

3.1. The QIMR Berghofer-HREC requires electronic submissions in a standard format for human ethical approvals.

3.2. With respect to human experimentation proposals, researchers must conform to the requirements of the "*National Statement"* and provide the information which will enable scientific and ethical evaluation of the protocols.

3.3. With respect to clinical trials protocols, researchers must also conform to the requirements of the "*Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) – Annotated with TGA Comments"* and provide the information which will enable clinical evaluation of the protocols.

3.4. A copy of the full research protocol for each project is available, on request, for inspection by any member of the QIMR Berghofer-HREC.

4. WORKING PROCEDURES

4.1. Frequency of Meetings

4.1.1. Between 8 and 12 meetings are held each year, depending upon the number and urgency of proposals. This ensures timely consideration and review of applications.

4.1.2. The QIMR Berghofer-HSSC and QIMR Berghofer-CTPC meet 2-4 weeks prior to the QIMR Berghofer-HREC meeting. Additional meetings of the subcommittees may be scheduled if required.

4.1.3. A timetable for meetings for the year will be promulgated by November of the preceding year and published on the QIMR Berghofer Intranet.

4.1.4. The Chairperson can reschedule a meeting, convene additional meetings to consider urgent matters, or cancel a meeting if there is insufficient business.

4.1.5. At the discretion of the HREC Chairperson, at least four HREC meetings per year will include an educational/research presentation/component related to matters under consideration by the HREC or of interest to the HREC.

4.2. Preparation of Agenda

The advertised deadlines allow time for an initial administrative consideration of research protocols and for review by the HSSC or CTPC to enable applicants to modify their applications after the HSSC/CTPC review prior to the QIMR Berghofer-HREC meeting.

4.3. Distribution of Materials Prior to Meetings

4.3.1. The Secretary distributes the agenda, research applications and relevant papers to all QIMR Berghofer-HREC members prior to the meeting, allowing sufficient time for reading.

4.3.2. Members may access protocols in electronic form via the QIMR Berghofer E-forms system.

4.4. Meetings and Methods of Decision Making

4.4.1. The quorum for a QIMR Berghofer-HREC meeting is the minimum membership as defined in 2.3 above.

4.4.2. Members who are unable to attend a meeting are encouraged to contribute their opinions prior to the meeting via written or oral submissions to the Secretary or Chairperson. If a member is unable to attend or contribute prior to the meeting, the Chairperson should be satisfied before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered.

4.4.3. Conflict of interest: Any member who has an interest or a conflict of interest in a research protocol before the Committee, including personal involvement or participation in the research, financial or other interest or affiliation, involvement in competing research, or as defined by the *QIMR Berghofer Policy: Conflict of Interest*, must declare the interest and its nature at the beginning of the meeting. When a research protocol involves a Committee member, that member, at the discretion of the Chairperson, may be required to leave the meeting before a final decision is taken.

4.4.4. Investigators may be invited to a meeting to clarify and represent their protocols or inform the HREC about their area of research as per 4.1.5.

4.4.5. Investigators may request to be present at a meeting for discussions of their proposed research.

4.4.6. In general, decisions by QIMR Berghofer-HREC are reached by general agreement rather than by majority vote. Where one or more committee members have serious concern about a project, that concern must be addressed before approval is given. Where a vote is taken, approval requires a majority of the Committee and a majority of external members who are present. An abstention is taken to be a vote against the proposal.

4.4.7. HREC approvals are normally for one year (subject to timely submission of the annual report) and, provided there are no concerns, renewed on review of the relevant annual report.

4.5. Expedited Review of Research Proposal Between QIMR Berghofer-HRECMeetings (Executive Approvals)

4.5.1. Although in general, all proposals must be submitted to the QIMR Berghofer-HREC for approval, the QIMR Berghofer-HREC has provision for expedited review of research proposals between meetings.

4.5.2. Executive approval process may be used in the following circumstances:

4.5.2.1. Where a deficiency is identified by the QIMR Berghofer-HREC or additional information is required, the QIMR Berghofer-HREC may authorise the Chairperson or Delegate to approve the proposal executively when the Chairperson or Delegate is satisfied that the deficiency has been addressed or the additional information has been provided.

4.5.2.2. Executive approval may be requested by PI to expedite approval of non-controversial amendments to an approved protocol, for example to approve amendments requested by another HREC, to update personnel on a project, to improve trial associated procedures, or to make technical modifications to test procedures.

4.5.2.3. Executive approval may be requested to expedite approval of minor amendments of administrative nature, for example changes of contact details, corrections of version control and/or page numbering, or correction of minor errors in approved documents.

4.5.3. Executive approval process is unlikely to be appropriate for a new protocol unless there is mutual acceptance agreement in place.

4.5.4. Requests for executive approval may be made through the Secretary to the Chairperson or any HREC Member, delegated to act as HREC Chairperson (the Delegate).

4.5.5. If the Chairperson (or Delegate) is satisfied that the submission meets the requirements for Expedited Approval/Executive Approval, the Chairperson (or Delegate) may:

4.5.5.1. Grant Executive Approval.

4.5.5.2. Refer the application to any other member or members of the QIMR Berghofer-HREC, the QIMR Berghofer-HSSC or the QIMR Berghofer

-CTPC for comment to assist the Chairperson (or Delegate) in deciding whether approval should be given.

4.5.5.3. Bypass the normal HREC review process by placing the request as a late item on the HREC agenda.

4.5.5.4. Request an out of session review by HREC ("Flying minute").

4.5.5.5. Call a special meeting of HREC.

4.5.5.6. Require amendment of the proposal.

4.5.5.7. Refuse the request for executive approval.

4.5.6. An executive approval is final and does not require further approval. All executive approvals will be submitted to the next meeting of the QIMR Berghofer-HREC for noting.

4.6. Preparation of Minutes and Recording of Decisions

4.6.1. To encourage free and open discussion and to emphasise the collegiate character of QIMR Berghofer-HREC deliberations, particular views of individual members are not recorded in the minutes unless specifically requested.

4.6.2. The minutes are produced as soon as practicable following the relevant meeting and checked by the Chairperson as a true and correct record. Copies of the minutes are sent to QIMR Berghofer-HREC members at least 7 days prior to the next meeting.

4.6.3. To assist with the preparation of minutes, the proceedings of HREC meetings may be recorded.

4.7. Prompt Notification of Decisions

The Secretary is responsible for communicating the HREC decisions to researchers by email via the E-forms system as soon as practicable following the committee meeting at which their research proposals have been discussed.

4.8. Researcher Compliance with Decisions

Researchers are expected to comply with decisions reached by the QIMR Berghofer-HREC and any other recommendations/conditions as required by collaborating HREC/s.

4.9. Multi-centre studies

4.9.1. Mutual Acceptance/Recognition Agreement/s

4.9.1.1. The QIMR Berghofer and QIMR Berghofer-HREC may make a formal mutual acceptance/recognition agreement with a collaborating institution and its HREC. Where such an agreement exists the ethics approval procedure will be set out in the agreement.

4.9.1.2. For a particular project, QIMR Berghofer-HREC and HREC/s of collaborating institutions may agree to adopt specific procedures for handling certain matters associated with the project, including review of Serious or Unexpected Adverse Events reports, and protocol deviations.

4.9.2. Other Multicentre Projects:

Unless QIMR Berghofer and QIMR Berghofer-HREC has a formal mutual acceptance/recognition agreement applicable to the project, QIMR Berghofer investigators are required to submit human research ethics applications in accordance with these terms of reference.

4.9.3. Principal investigators must notify the QIMR Berghofer-HREC:

4.9.3.1. If collaborating HREC/s approve a project subject to any provisos or reservations.

4.9.3.2. If another HREC has refused to approve the project.

4.9.4. Where there is a disagreement between HRECs, QIMR Berghofer-HREC will work collaboratively with Principal Investigators and collaborating HREC/s to resolve matters.

4.9.5. Advice to HRECs of Collaborating Research Institutes

QIMR Berghofer-HREC may communicate directly with HRECs of collaborating institutions concerning any issue relating to approval, adverse events.

4.10. Reporting of Changes to Protocol

Researchers are required to report anything that might warrant review of ethical approval of the protocol, including:

4.10.1. Deviations from the protocol.

4.10.2. Withdrawal of approval by another HREC or institution.

4.10.3. New information and/or unforeseen events that might affect continued ethical acceptability of the project.

4.10.4. Allegation or suspicion of scientific fraud.

4.11. Reporting of Serious Adverse Events

All researchers are required to immediately report anything that might warrant review of ethical approval of the protocol, including:

4.11.1. Serious or unexpected adverse effects on participants.

4.11.2. Any information that would indicate an increased risk to participants.

4.12. Monitoring

4.12.1. The QIMR Berghofer-HREC requires:

4.12.1.1. Adequate records to be maintained for all human experimentation protocols.

4.12.1.2. Regular reports from principal investigators, at least annually.

4.12.1.3. Immediate reports in the event of serious or unexpected adverse effects on participants.

4.12.1.4. Proposed changes in the protocol to be submitted for approval before implementation.

4.12.1.5. Immediate reports about any unforeseen events that might affect continued ethical acceptability of the project.

4.12.1.6. Reports from researchers if the research project is discontinued before the expected date of completion, giving reasons.

4.12.1.7. Reports from other staff or personnel in QIMR Berghofer, as necessary.

4.12.1.8. Request that the QIMR Berghofer Regulatory Affairs staff conduct project reviewsReports/reviews from external experts, if required.

4.12.1.9. Notification of published results/research publications.

4.12.2. If considered necessary, the QIMR Berghofer-HREC may take action to ensure that a project is undertaken in accordance with the terms of an approval including, but not limited to requiring a report from the Principal Investigator, interviewing the researcher/s or research subjects, inspecting the laboratory and commissioning an external review of the project.

4.13. Complaints, Receiving and Handling

4.13.1. Subject to any agreement under clause 4.9.1, participants or subjects in projects approved by the QIMR Berghofer-HREC must be provided with contact details which allow them to address complaints or concerns about the research to the QIMR Berghofer-HREC Chairperson or Secretary.

4.13.2. Complaints on the process of ethics review, project conduct or decisions of the QIMR Berghofer-HREC should be made in writing to the Chairperson of the QIMR Berghofer-HREC via the Secretary.

4.13.3. The Chairperson will acknowledge the receipt of the complaint to the complainant within seven days.

4.13.4. The Chairperson will consider the complaint and will determine a course of action.

4.13.5. The complaint and the proposed action will be reported to the next meeting of the QIMR Berghofer-HREC.

4.13.6. In the event that the response to the complaint has not been finalised within 60 days, the complainant will be notified in writing of progress.

4.13.7. If the complainant does not accept the decision of the QIMR Berghofer-HREC Chairperson, then further consideration may be obtained by addressing the complaint to the QIMR Council.

4.14. Discontinuation of Research Projects

In cases of non-compliance and/or where circumstances warrant that a research project should be discontinued, the QIMR Berghofer-HREC will recommend to QIMR Berghofer Director and QIMR Berghofer Management and the collaborating research institute/s that the research project be discontinued or suspended.

4.15. Fees and Charges

QIMR Berghofer levies fees for ethical review of commercially sponsored studies. A schedule of the fees is available on the QIMR Berghofer Intranet.

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[Note: All above as amended from time to time]